APPENDIX - A

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the office electronic filing system in accordance with § 1.6(a)(4). on the date shown below.

Dated: October 26, 2009
Electronic Signature for Elizabeth A. Hanley: /Elizabeth A. Hanley/

Docket No. 117750-01801
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Kenneth Powell *et al.*

Confirmation #: 2807

Application No. 10/593,666

Filed: March 12, 2007

Art Unit: 1617

For: **PHARMACEUTICAL COMPOSITION COMPRISING A BENZODIAZEPINE DERIVATIVE AND AN INHIBITOR OF THE RSV FUSION PROTEIN**

Examiner: PIHONAK, Sarah

Mail Stop Amendment
Commissioner for Patents
Post Office Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

In response to the Restriction Requirement set forth in the Office communication dated May 6, 2009 (Paper No.: 20090422), please amend the above-identified U.S. patent application as indicated below.

Amendment to the Claims begin on page 2 of this paper.

Remarks begin on page 23 of this paper.

Amendments to the Claims

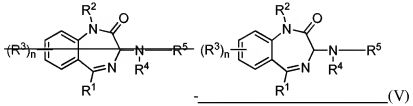
This claim set replaces all previous claims in this application.

1. (Original) A pharmaceutical composition which comprises a pharmaceutically acceptable carrier or diluent and:

(a) an inhibitor of the RSV fusion protein; and

(b) a benzodiazepine derivative capable of inhibiting RSV replication.

2. (Currently amended) A composition according to claim 1, wherein component (b) is a compound of formula (V), or a pharmaceutically acceptable salt thereof,



(V)

wherein:

R^1 represents C_{1-6} alkyl, aryl or heteroaryl;

R^2 represents hydrogen or C_{1-6} alkyl;

each R^3 is the same or different and represents halogen, hydroxy, C_{1-6} alkyl, C_{1-6} alkoxy, C_{1-6} alkylthio, C_{1-6} haloalkyl, C_{1-6} haloalkoxy, amino, mono(C_{1-6} alkyl)amino, di(C_{1-6} alkyl)amino, nitro, cyano, -CO_2R', -CONR'R'', -NH-CO-R', -S(O)R', -$S(O)_2$R', -NH-$S(O)_2$R', -S(O)NR'R" or -$S(O)_2$NR'R", wherein each R' and R" is the same or different and represents hydrogen or C_{1-6} alkyl;

n is from 0 to 3;

R^4 represents hydrogen or C_{1-6} alkyl;

R^5 represents C_{1-6} alkyl, aryl, heteroaryl, carbocyclyl, heterocyclyl, aryl-(C_{1-6} alkyl)-, heteroaryl-(C_{1-6} alkyl)-, carbocyclyl-(C_{1-6} alkyl)-, heterocyclyl-(C_{1-6} alkyl)-, aryl-(C_{1-6} hydroxyalkyl)-, heteroaryl-(C_{1-6} hydroxyalkyl)-, carbocyclyl-(C_{1-6} hydroxyalkyl)-, heterocyclyl-(C_{1-6} hydroxyalkyl)-, aryl-C(O)-C(O)-, heteroaryl-C(O)-C(O)-, carbocyclyl-C(O)-C(O)-, heterocyclyl-C(O)-C(O)- or -XR^6;

X represents -CO-, -S(O)- or -$S(O)_2$-; and

R^6 represents C_{1-6} alkyl, hydroxy, C_{1-6} alkoxy, C_{1-6} alkylthio, aryl, heteroaryl, carbocyclyl, heterocyclyl, aryl-(C_{1-6} alkyl)-, heteroaryl-(C_{1-6} alkyl)-, carbocyclyl-(C_{1-6} alkyl)-, heterocyclyl-(C_{1-6} alkyl)-, aryl-(C_{1-6} alkyl)-O-, heteroaryl-(C_{1-6} alkyl)-O-, carbocyclyl-(C_{1-6} alkyl)-O-, heterocyclyl-(C_{1-6} alkyl)-O- or -NR'R" wherein each R' and R" is the same or different and represents hydrogen, C_{1-6} alkyl, carbocyclyl, heterocyclyl, aryl, heteroaryl, aryl-(C_{1-6} alkyl)-, heteroaryl-(C_{1-6} alkyl)-, carbocyclyl-(C_{1-6} alkyl)- or heterocyclyl-(C_{1-6} alkyl)-.

3. (Original) A composition according to claim 2 wherein:

each R^3 is the same or different and represents halogen, hydroxy, C_{1-6} alkyl, C_{1-6} alkoxy, C_{1-6} alkylthio, C_{1-6} haloalkyl, C_{1-6} haloalkoxy, amino, mono(C_{1-6} alkyl)amino, di(C_{1-6} alkyl)amino, nitro, cyano, -CO_2R', -CONR'R", -NH-CO-R', -S(O)R', -$S(O)_2$R', -NH-$S(O)_2$R' or -S(O)NR'R", wherein each R' and R" is the same or different and represents hydrogen or C_{1-6} alkyl ;

R represents C_{1-6} alkyl, aryl, heteroaryl, carbocyclyl, heterocyclyl, aryl-(C_{1-6} alkyl)-, heteroaryl-(C_{1-6} alkyl)-, carbocyclyl-(C_{1-6} alkyl)-, heterocyclyl-(C_{1-6} alkyl)- or -XR^6;

X represents -CO-, -S(O)- or -$S(O)_2$-; and

R^6 represents C_{1-6} alkyl, hydroxy, C_{1-6} alkoxy, C_{1-6} alkylthio, aryl, heteroaryl, carbocyclyl, heterocyclyl, aryl-(C_{1-6} alkyl)-, heteroaryl-(C_{1-6} alkyl)-, carbocyclyl-(C_{1-6} alkyl)-, heterocyclyl-(C_{1-6} alkyl)- or -NR'R" wherein each R' and R" is the same or different and represents hydrogen, C_{1-6} alkyl, carbocyclyl, heterocyclyl, aryl, heteroaryl, aryl-(C_{1-6} alkyl)- or heteroaryl-(C_{1-6} alkyl)-.

4. (Previously presented) A composition according to claim 2, wherein R^1 is C_{1-2} alkyl or aryl.

5. (Previously presented) A composition according to claim 2 wherein R^2 is hydrogen.

6. (Previously presented) A composition according to claim 2 wherein R^3 is halogen, hydroxy, C_{1-4} alkyl, C_{1-4} alkoxy, C_{1-4} alkylthio, C_{1-4} haloalkyl, C_{1-4} haloalkoxy, amino, mono(C_{1-4} alkyl)amino or di(C_{1-4} alkyl)amino.

7. (Original) A composition according to claim 6, wherein R^3 is fluorine, chlorine, bromine, C_{1-2} alkyl, C_{1-2} alkoxy, C_{1-2} alkylthio, C_{1-2} haloalkyl, C_{1-2} haloalkoxy, amino, mono(C_{1-2} alkyl)amino or di (C_{1-2} alkyl)amino.

8. (Previously presented) A composition according to claim 2 wherein R^4 is hydrogen or C_{1-2} alkyl.

9. (Previously presented) A composition according to claim 2 wherein R^5 is C_{1-6} alkyl, aryl, heteroaryl, carbocyclyl, heterocyclyl, aryl-(C_{1-4} alkyl)-, heteroaryl-(C_{1-4} alkyl)-, carbocyclyl-(C_{1-4} alkyl)-, heterocyclyl- C_{1-4} alkyl)-, aryl-C(O)-C(O)-, heteroaryl-C(O)-C(O)- or -XR^6.

10. (Original) A composition according to claim 9, wherein R^5 is C_{1-4} alkyl, aryl, heteroaryl, carbocyclyl, heterocyclyl, phenyl-(C_{1-2} alkyl)-, heteroaryl-(C_{1-2} alkyl)-, phenyl-C(O)-C(O)-, heteroaryl-C(O)-C(O)- or -XR^6.

11. (Original) A composition according to claim 10, wherein R^5 is C_{1-4} alkyl, phenyl, thienyl, furanyl, isoxazolyl, pyridyl, cyclopentyl, cyclohexyl, benzothienyl, dihydrobenzofuranyl, phenyl-CH_2-, furanyl-CH_2-, phenyl-C(O)-C(O)-, thienyl-C(O)-C(O)- or -XR^6.

12. (Previously presented) A composition according to claim 2 wherein, X is -CO- or -$S(O)_2$-.

13. (Previously presented) A composition according to claim 2 wherein, when R^6 is a group NR'R" wherein each R' and R" is the same or different and represents hydrogen, C_{1-4} alkyl, aryl, carbocyclyl, heterocyclyl, aryl-(C_{1-4} alkyl)- or heteroaryl-(C_{1-4} alkyl)-.

14. (Original) A composition according to claim 13, wherein when R^6 is a group –NR'R" each R' and R" is the same or different and represents hydrogen, C_{1-4} alkyl, phenyl, thienyl, cyclohexyl, cyclopentyl or phenyl-CH_2-.

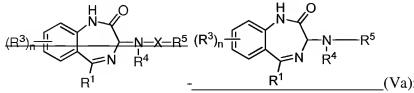
15. (Original) A composition according to claim 14, wherein when R^6 is a group –NR'R" and one of R' and R" is hydrogen.

16. (Previously presented) A composition according to claim 2 wherein R^6 is C_{1-6} alkyl, hydroxy, C_{1-6} alkoxy, C_{1-6} alkylthio, aryl, heteroaryl, carbocyclyl, heterocyclyl, aryl-(C_{1-4} alkyl)-, heteroaryl-(C_{1-4} alkyl)-, carbocyclyl-(C_{1-4} alkyl)-, heterocyclyl-(C_{1-4} alkyl)-, aryl-(C_{1-4} hydroxyalkyl)-, heteroaryl-(C_{1-4} hydroxyalkyl)-, carbocyclyl-(C_{1-4} hydroxyalkyl)-, heterocyclyl-(C_{1-4} hydroxyalkyl)-, aryl-(C_{1-4} alkyl)-O-, heteroaryl-(C_{1-4} alkyl)-O-, carbocyclyl-(C_{1-4} alkyl)-O-, heterocyclyl-(C_{1-4} alkyl)-O- or –NR'R".

17. (Original) A composition according to claim 16, wherein R^6 is C_{1-6} alkyl, C_{1-6} alkoxy, C_{1-6} alkylthio, aryl, heteroaryl, carbocyclyl, heterocycly, phenyl-(C_{1-2} alkyl)-, phenyl-(C_{1-2} alkyl)-O-, heteroaryl-(C_{1-2} alkyl)-, phenyl-(C_{1-2} hydroxyalkyl)-, heteroaryl-(C_{1-2} hydroxyalkyl)- or -NR'R".

18. (Original) A composition according to claim 17, wherein R^6 is C_{1-4} alkyl, C_{1-4} alkoxy, phenyl, naphthyl, dihydrobenzofuranyl, benzodioxinyl, 9H-fluoren-9-onyl, indolyl, thienyl, furanyl, oxazolyl, isoxazolyl, pyrazolyl, pyridyl, benzothienyl, benzofuranyl, cyclopentyl, cyclohexyl, piperazinyl, piperidinyl, morpholinyl, phenyl-(C_{1-2} alkyl)-, phenyl-CH_2-CH(OH)-, phenyl-CH(OH)-CH_2-, phenyl-(C_{1-2} alkyl)-O-, 1H-benzo[d]imidazol-2(3H)-onyl or –NR'R".

19. (Currently amended) A composition according to claim 2 wherein the benzodiazepine derivative of formula (V) is a benzodiazepine derivative of formula



(Va):

wherein:

R^1 is phenyl or methyl;

R^3 is methyl or chlorine;

n is 0 or 1;

R^4 is hydrogen or methyl;

R^5 is phenyl-CH_2-, furanyl-CH_2-, thienyl-C(O)-C(O)- or -XR^6;

X is -CO- or -$S(O)_2$-; and

R^6 is C_{1-4} alkyl, C_{1-4} alkoxy, phenyl, naphthyl, dihydrobenzofuranyl, benzodioxinyl, 9H-fluoren-9-onyl, indolyl, thienyl, furanyl, oxazolyl, isoxazolyl, pyrazolyl, pyridyl, benzothienyl, benzofuranyl, cyclopentyl, cyclohexyl, piperazinyl, piperidinyl, morpholinyl, phenyl-(C_{1-2} alkyl)-, phenyl-CH_2-CH(OH)-phenyl-CH(OH)-CH_2-, phenyl-(C_{1-2} alkyl)-O-, lH-benzo[d]imidazol-2(3H)-onyl or -NR'R" wherein each R' and R" is the same or different and represents hydrogen, C_{1-4} alkyl, phenyl, thienyl, cyclohexyl, cyclopentyl or phenyl-(CH_2)-, the phenyl moiety in the group R^1 being unsubstituted or substituted by a single fluorine, chlorine, C_{1-2} alkyl, C_{1-2} alkoxy, C_{1-2} alkylthio, C_{1-2} haloalkyl or C_{1-2} haloalkoxy substituent;

the aryl moieties in the groups R^5 and R^6 being unsubstituted or substituted by 1, 2 or 3 substituents selected from fluorine, chlorine, bromine, iodine, C_{1-4} alkyl, C_{2-4} acyl, hydroxy, C_{1-4} alkoxy, C_{1-4} alkylthio, C_{1-4} haloalkyl, C_{1-4} haloalkoxy, amino, mono(C_{1-4} alkyl)amino, di(C_{1-4} alkyl)amino, nitro, -CO_2R', -$S(O)_2$R' and -$S(O)_2NH_2$, wherein R' represents C_{1-2} alkyl;

the heteroaryl moieties in the groups R^5 and R^6 being unsubstituted or substituted by 1 or 2 substituents selected from fluorine, chlorine, bromine, C_{1-2} alkyl, C_{1-2} haloalkyl and di(C_{1-2} alkyl)amino; and

the heterocyclyl and carbocyclyl moieties in the R^6 group being unsubstituted or substituted by 1 or 2 substituents selected from fluorine, chlorine, bromine, C_{1-4} alkyl, C_{1-4} alkoxy, C_{1-4} haloalkyl and nitro.

20. (Original) A composition according to claim 1, wherein the benzodiazepine derivative of formula (V) is:

Cyclohexanecarboxylic acid 2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-amide;

3-Methoxy N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl)-benzamide;

4-Methoxy N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Methoxy N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

N-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-trifluoromethyl-benzamide;

N-(2-Oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

Thiophene-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-3-amide;

Furan-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-amide;

Piperidine-1-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-amide;

Morpholine-4-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3 -yl)-amide;

4-Nitro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

3-Nitro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

4-Methyl-piperazine-l-carboxylic acid-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-amide;

3,4-Dichloro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-2-trifluoromethyl-benzamide;

4-Bromo-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Methyl-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Chloro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Nitro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Methoxy-4-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

(S)-2-Methoxy-4-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-benzamide

Benzo[b]thiophene-3-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-l H-benzo[e] [1,4]diazepin-3-yl)-amide;

2,3-Dihydro-benzofuran-5-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][l,4]diazepin-3-yl)-amide;

Isoxazole-5-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-amide;

Benzo[b]thiophene-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-amide;

Thiophen-3-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-amide;

N-(2-Oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-isonicotinamide;

N-(2-Oxo-5 -phenyl-2,3-dihydro-1 H-benzo [e][1,4] diazepin-3-yl)-nicotinamide;

N-(2-Oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-methanesulfonamide;

Propane-1-sulfonic acid-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-amide;

Butane-l-sulfonic acid-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-amide;

2-Bromo-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzenesulfonamide;

3-Bromo-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzenesulfonamide;

4-Bromo-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzenesulfonamide;

2-Fluoro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzenesulfonamide;

3-(2-Nitro-benzylamino)-5-phenyl-1,3-dihydro-benzo[e][1,4]diazepin-2-one;

3-(3-Nitro-benzylamino)-5-phenyl-l,3-dihydro-benzo[e][l,4]diazepin-2-one;

3-(4-Nitro-benzylamino)-5-phenyl-1,3-dihydro-benzo[e][1,4]diazepin-2-one;

3-(2-Methoxy-benzylamino)-5-phenyl-1,3-dihydro-benzo[e][1,4]diazepin-2-one;

3-(3-Methoxy-benzylamino)-5-phenyl-l,3-dihydro-benzo[e][l,4]diazepin-2-one;

5-Phenyl-3-(2-trifluoromethyl-benzylamino)-l,3-dihydro-benzo[e][l,4]diazepin-2-one;

5-Phenyl-3-(3-trifluoromethyl-benzylamino)-1,3-dihydro-benzo[e][1,4]diazepin-2-one;

5-Phenyl-3-(4-trifluoromethyl-benzylamino)-1,3-dihydro-benzo[e][l,4]diazepin-2-one;

3-[(Furan-2-ylmethyl)-amino]-5-phenyl-l,3-dihydro-benzo[e][l,4]diazepin-2-one;

N-(7-Chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-acetamide;

N-(7-Chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-isobutyramide;

N-(7-Chloro-2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-methanesulfonamide;

Furan-2-carboxylic acid (7-chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-amide;

Thiophene-2-carboxylic acid (7-chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e] [1,4]diazepin-3-yl)-amide;

Cyclohexanecarboxylic acid (7-Chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e] [1,4]diazepin-3-yl)-amide;

N-(7-Chloro-2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-2-methoxy-benzamide;

N-(7-Chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-4-methoxy-benzamide;

N-(7-Chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-2-nitro-benzamide;

2-(2-Methoxy-phenyl)N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-acetamide;

2-(3-Methoxy-phenyl)N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-acetamide;

2-(4-Methoxy-phenyl)N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-acetamide;

2-(4-Nitro-phenyl)N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-acetamide;

2-(3-Nitro-phenyl)N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-acetamide;

N-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-2-(2-trifluoromethyl-phenyl)-acetamide;

N-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-2-(3-trifluoromethyl-phenyl)-acetamide;

N-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-2-(4-trifluoromethyl-phenyl)-acetamide;

l-(2-Methoxy-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-urea;

l-(2-Nitro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-urea;

1-(2-Chloro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl)-urea;

1-(4-Chloro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl-urea;

1-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-p-tolyl-urea;

1-(2-Fluoro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-urea;

1-(4-Fluoro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4] diazepin-3-yl)-urea;

(S)-l-(2-Fluoro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-urea;

4-Methanesulfonyl-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e] [1,4]diazepin-3-yl)-benzamide;

(S)-4-Methanesulfonyl-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

5-Acetyl-2-ethoxy-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

(S)-5-Acetyl-2-ethoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-benzamide;

6-Fluoro-4H-benzo[l,3]dioxine-8-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-amide;

(S)-6-Fluoro-4H-benzo[l,3]dioxine-8-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-amide;

(S)-2-Methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-4-trifluoromethyl-benzamide;

2,4,5-Trifluoro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

(S)-2,4,5-Trifluoro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Hydroxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

(S)-2-Hydroxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

1H-Indole-7-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-amide;

(S)-1H-Indole-7-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-amide;

3-Methoxy-naphthalene-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-amide;

(S)-3-Methoxy-naphthalene-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-amide;

N-[7-Chloro-5-(2-fluoro-phenyl)-2-oxo-2,3-dihydro-lH-benzo[e][l,4]diazepine-3-yl]-4-methoxoy-benzamide;

1-(2-Fluoro-benzyl)-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl)-urea;

1-(4-Methoxy-benzyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4] diazepin-3-yl)-urea;

1-(3-Methyl-benzyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-urea;

l-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-(4-trifluoromethyl-phenyl)-urea;

4-Chloro-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

4-Methoxy-3-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)benzamide;

3-Methoxy-2-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

5-Chloro-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)benzamide;

5-Fluoro-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Methoxy-4-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

5-Methoxy-2-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

3-Methoxy-4-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

3-(2-Methoxy-phenyl)-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl)propionamide;

3-(3-Methoxy-phenyl)-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-propionamide;

3-(4-Methoxy-phenyl)-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-propionamide;

N-[5-(3-Chloro-phenyl)-2-oxo-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-2-methoxy-benzamide;

N-[5-(3-Chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-4-methoxy-benzamide;

N-[5-(3-Chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-2-nitro-benzamide;

N-[5-(3-Chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-4-nitro-benzamide;

4-Methoxy-N-[2-oxo-5-(4-trifluoromethyl-phenyl)-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-benzamide;

2-Methoxy-N-[2-oxo-5-(3-trifluoromethyl-phenyl)-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl]-benzamide;

4-Methoxy-N-[2-oxo-5-(3-trifluoromethyl-phenyl)-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl]-benzamide;

2-Ethoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-benzamide;

2,4-Dimethoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Bromo-5-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Methoxy-N-[5-(3-mehtoxy-phenyl)-2-oxo-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-benzamide

N-[5-(3-Methoxy-phenyl)-2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl]-4-nitro-benzamide;

2-Methoxy-N-(8-methyl-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Chloro-4-methanesulfonyl-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Dimethylamino-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

(2-Oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-carbamic acid benzyl ester;

l-(3,5-Dimethyl-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-urea;

l-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-(4-trifluoromethoxy-phenyl)-urea;

1-(4-Bromo-2-trifluoromethyl-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][l,4]diazepin-3-yl)-urea;

l-(4-Bromo-benzyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-urea;

l-(2,3-Dichloro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3 -yl)-urea;

1-(2,6-Dimethyl-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-urea;

l-(2-Chloro-6-methyl-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-urea;

1-(4-Nitro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-urea;

l-(2-Methylsulfanyl-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-urea;

l-(2,6-Dichloro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-urea;

5-tert-Butyl-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2,5-Dimethoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

1 -(2,6-Difluoro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-urea;

l-(3-Fluoro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-urea;

l-(3-Methoxy-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-urea;

l-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-(3-trifluoromethyl-phenyl)-urea;

l-(3-Chloro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e]1,4]diazepin-S-yl)-urea;

2-Methoxy-4-methylsulfanyl-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

4-Methanesulfonyl-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

N-(2-Oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl)terephthalamic acid methyl ester;

2-Fluoro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

2,6-Difluoro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

N-(2-Oxo-5-phenyl-2, 3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-2-propoxy-benzamide;

2-Iodo-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl)-benzamide;

3-Methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-terephthalamic acid methyl ester;

4-Amino-5-chloro-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-benzamide;

l-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-m-tolyl-urea;

2-Methylsulfanyl-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

2-Methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-5-sulfamoyl-benzamide;

2-Hydroxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-phenyl-propionamide

3-Hydroxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-phenyl-propionamide;

3-(2-Fluoro-phenyl)-l-methyl-1-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-urea;

2-Methoxy-N-methyl-4-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

1-tert-Butyl-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-urea;

1-Cycloheyl-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-urea;

1-Ethyl-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-urea;

1-Butyl-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-urea;

4,5-Dimethyl-furan-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)amide;

Piperidine-1-carboxylic acid (7-chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-amide;

N-[5-(3-Chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)acetamide;

N-[5-(3-Chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-isobutyramide;

Furan-2-carboxylic acid [5-(3-chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][l,4]diazepin-3-yl]-amide;

Thiophene-2-carboxylic acid [5-(3-chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-amide;

Cyclohexanecarboxylic acid [5-(3chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-amide;

Piperidine-1-carboxylic acid [5-(3-chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-amide;

N-[5-(3-Chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]isonicotinamide;

5-Methyl-furan-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e] [1,4] diazepin-3-yl)-amide;

Pyrazine-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-amide;

N-[5-(3-Methoxy-phenyl)-2-oxo-5-phenyl2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl]-isobutyramide;

Thiophene-2-carboxylic acid [5-(3-methoxy-phenyl)-2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl] -amide;

Cyclohexanecarboxylic acid [5-(3-methoxy-phenyl)-2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][l,4]diazepin-3-yl]-amide;

Piperidine-1-carboxylic acid [5-(3-methoxy-phenyl)-2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl]-amide;

Piperidine-4-carboxylic acid [5-(3-methoxy-phenyl)-2-oxo-5-phenyl-2,3-dihydro-1 H-benzo[e][l,4]diazepin-3-yl]-amide;

Cyclohexanecarboxylic acid (8-chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e] [l,4]diazepin-3-yl)-amide;

Thiophene-2-carboxylic acid (8-methyl-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-amide;

l-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-thiophene-2-yl-urea;

1-(2-Oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-thiophene-3-yl-urea;

Pyridine-2 -carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l ,4] diazepin-3-yl)-amide;

1H-Pyrazole-4-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-l H-benzo[e] [1 ,4] diazepin-3-yl)-amide;

6-Dimethylamino-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-nicotinamide;

2-Ethoxy-naphthalene-l -carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-amide;

9-Oxo-9H-fluorene-l -carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e] [1,4]diazepin-3-yl)-amide;

2-Oxo-2,3-dihydro-benzoimidazole-1 -carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][l,4]diazepin-3-yl)-amide;

(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)carbamic acid tert-butyl ester;

(S)-4,5-Dibromo-furan-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1 ,4]diazepin-3-yl)-amide;

(S)-Benzofuran-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e] [1 ,4]diazepin-3-yl)-amide;

(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-carbamic acid methyl ester;

(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l ,4]diazepin-3-yl)-carbamic acid ethyl ester;

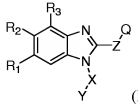
(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-carbamic acid isobutyl ester; and

2-Oxo-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl)-2-thiophene-2-yl-acetamide.

21. (Previously presented) A composition according to claim 2, wherein the benzodiazepine derivative of formula (V) is l-(2-fluoro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-urea, 2-methoxy-4-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide or 4-methanesulfonyl-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3 -yl)-benzamide.

22. (Original) A composition according to claim 21, wherein the benzodiazepine derivative of formula (V) is l-(2-fluoro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-urea.

23. (Currently amended) A composition according to claim 1, wherein component (a) is a compound of formula (I), or a pharmaceutically acceptable salt thereof,



(I)

wherein:

X is a direct link or C_{1-6} alkyl; said C_{1-6} alkyl being optionally substituted with halogen, oxo, cyano, hydroxyl, $OCOR_4$ or $S(O)_n$-C_{1-6} alkyl;

Y is R_4, NR_4R_5, $NCOR_4$, =N-OR_4, -$CONHR_4$, $COOR_4$, -OR_4, aryl, heteroaryl, cyclyl or heterocyclyl, where R_4 and R_5 are H or C_{1-6} alkyl;

Z is CR_6R', where R_6 and R' are independently H, or straight, branched or cyclic C_{1-6} alkyl;

n is 1-2;

R_1 is H, $CONR_4R_5$, CO_2R_4 or C_{1-6} alkyl, said C_{1-6} alkyl can be optionally substituted with OR_4 or NR_8R_9;

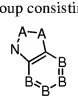
R_8 and R_9 are each independently H, C_{1-6} alkyl, SO_2R_5, CO_2R_4 or COR_4;

R_2 is selected from the group consisting of H, NH_2, $CONR_6R'$, heteroaryl, C_{2-6} alkenyl, CO_2R_4, N=CPh_2, C(=NH)NH_2 and C_{1-6} alkyl; said alkyl optionally substituted with a member selected from the group consisting of halogen, CN, $NR_{10}R_{11}$, OSO_2R_4 and OR_4;

R_{10} and R_{11} are each independently selected from the group consisting of H, C_{1-6} alkyl, C_{3-6} cycloalkyl, CO_2R_4, COR_4 and SO_2R_4;

R_3 is selected from the group consisting of (1) CO_2R_9; (2) C_{1-6} alkyl optionally substituted with CN, OR_4 or NR_6R'; (3) H; and ~~(3)~~ (4) C_{2-6} alkenyl substituted with CN;

Q is a member selected from the group consisting of



A is C or N, optionally substituted with H, halogen, C_{1-6} alkyl, C_{2-6} alkenyl, cyano-C_{1-6} alkyl, CO_2R_4, aryl, benzoaminocarbonyl, hydroxybenzyl, $SO_2NR_4R_5$ or C_{3-6} cycloalkyl. Where A is carbon, it may also be optionally substituted by O or S via a double bond;

B is C or N; where B is C it may be optionally substituted by H, C_{1-6} alkyl, NO_2, CN, halogen, COR_4, $COOR_4$, $CONHR_4C(=NH)NH_2$ or C(=N0H)NH_2.

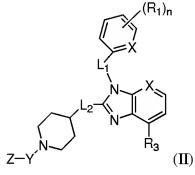
24. (Previously presented) A composition according to claim 23, wherein at least two of R_1, R_2 and R_3 are hydrogen, and the other is hydrogen or -C(NH)-NH_2 and/or either -X-Y is H, or X

is a C_1-C_6 alkylene group which is unsubstituted or substituted by a hydroxy group and Y is H, OH, CN, -NR'R", -COR', -SO_2R' or phenyl, wherein R' and R" are the same or different and represent a C_1-C_4 alkyl group and/or Z is -CH_2- and/or Q is a moiety

or


wherein B is -CH- or -N-, A_1 is -C(O)- or -NH- and A_2 is -CH_2-, -CHR'- or –NR"-, wherein R' is a halogen atom and R" represents a hydrogen atom or a C_{1-4} alkyl, C_{2-4} alkenyl, C_{3-6} cycloalkyl, -SO_2-(C_{1-6} alkyl), -SO_2-N(C_{1-6} alkyl)$_2$ or -(CO-NH)$_a$-(C_{1-4} alkyl)-phenyl group, wherein a is 0 or 1, which group is unsubstituted or is substituted with a hydroxy or cyano substituent.

25. (Previously presented) A composition according to claim 1, wherein component (a) is a compound of the formula (II), or a pharmaceutically acceptable salt thereof



(II)

wherein:

L_1 is -CH_2- or -CHR_2-CO-

each X is the same or different and is CH or N;

each R_1 is the same or different and is C_{1-6} alkyl, halogen, hydroxy, phenyl or $(CH_2)_m$=NH_2;

n is 1 or 2;

R2 is C_{1-6} alkoxy or C_{1-6} alkoxy-phenyl;

R3 is C_{1-6} alkyl;

L2 is -CH_2- or -NH-;

Y is C_{1-6} alkyl or C_{1-6} alkenyl;

Z is H, $N(R_4)2$-, -C(=O)-R_5, -C(=CH_2)-R_5, -CH(OH)-R_5, -CH(CH_3)-R_5, -CH(OCH_3)- R_5; each R_4 is the same or different and is H, C1-6 alkyl.

R_5 is C_{1-6}alkyl-carbonyl, amino, hydroxyl, aryl, heteroaryl, carbocyclyl, heterocyclyl; and

m = 1-6

26. (Previously presented) A composition according to claim 1, wherein component (a) is:

l-Cyclopropyl-3-[1-(4-hydroxy-butyl)-lH-benzoimidazol-2-ylmethyl]-l,3-dihydro-imidazo[4, 5-c]pyridin-2-one

{2-[2-(l,2-Dihydro-benzotriazol-l-ylmethyl)-benzoimidazol-l-yl]ethyl}-diethyl-amine

{2-[2-(3-Iodo-2,3-dihydro-indazol-l-ylmethyl)-benzimidazol-1-yl]-ethyl}-dimethyl-amine

1-Isopropenyl-3-[1-(3-methyl-butyl)-1H-benzoimidazol-2-ylmethyl]-l,3-dihydro-benzoimidazol-2-one

1-(4-Hydroxy-benzyl)-3-[1-(3-methyl-butyl)-lH-benzoimidazol-2-ylmethyl]-1,3-dihydro-benzoimidazol-2-one

l-Isopropenyl-3-[l-(3-oxo-butyl)-lH-benzoimidazol-2-ylmethyl]-l,3-dihydro-benzoimidazol-2-one

l-Ethyl-3-[l-(2-hydroxy-2-phenyl-ethyl)-lH-benzoimidazol-2-ylmethyl]-l,3-dihydro-benzoimidazol-2-one

l-Ethyl-3-[l-(4-hydroxy-butyl)-lH-benzoimidazol-2-ylmethyl]-l,3-dihydro-benzoimidazol-2-one

7-[2-(3-Isopropenyl-2-oxo-2,3-dihydrobenzoimidazol-l-ylmethyl)-benzoimidazol-l-yl]-heptanenitril

5-{3-[l-(3-Methanesulfonyl-propyl)-lH-benzoimidazol-2-ylmethyl]-2-oxo-2,3-dihydro-benzoimidazol-1-yl}-pentanenitrile

3-[l-(3-Methyl-buty)-lH-benzoimidazol-2-ylmethyl]-2-oxo-2,3-dihydro-benzoimidazol-1-carboxylic acid benzylamide

1-Methanesulfonyl-3-[1 -(3-methyl-butyl)-1H-benzoimidazol-2-ylmethyl]-1,3-dihydro-benzoimidazol-2-one

3-[1-(3-Methyl-butyl)-1H-benzoimidazol-2-ylmethyl]-2-oxo-2,3-dihydro-benzoimidazol-1 -sulfonic acid dimethylamide

l-Isopropenyl-3-(l-propyl-lH-benzoimidazol-2-ylmethyl)-l,3-dihydro-imidazo[4,5-c]pyridine-2-one

Bis(5-amidino-2-benzimidazolyl)-methane

2-{2-[1-[1-(2-Amino-ethyl)-piperidin-4-ylamino]-4-methyl-benzoimidazol-1-ylmethyl}-6-methyl-pyridin-3-ol

or a pharmaceutically acceptable salt thereof.

27. (Previously presented) A composition according to claim 1, wherein component (a) is 1-cyclopropyl-3-[1-(4-hydroxy-butyl)-1H-benzoimidazol-2-ylmethyl]-1 ,3-dihydro-imidazo[4,5-c]pyridin-2-one, {2-[2-(1 ,2-dihydro-benzotriazol-1-ylmethyl)-benzoimidazol-1-yl]] ethyl}-diethyl-amine, {2-[2-(3-iodo-2,3-dihydro-indazol-l-ylmethyl)-benzimidazol-l-yl]-ethyl}-dimethyl-amine or a pharmaceutically acceptable salt thereof.

28. (Previously presented) A composition according to claim 1, wherein component (a) is 1-cyclopropyl-3-[1-(4-hydroxy-butyl)-1H-benzoimidazol-2-ylmethyl]-1,3-dihydro-imidazo[4,5-c]pyridin-2-one or l-Isopropenyl-3-(l-propyl-lH-benzoimidazol-2-ylmethyl)-1,3-dihydro-imidazo[4,5-c]pyridine-2-one or a pharmaceutically acceptable salt thereof.

29. (Previously presented) A composition according to claim 1, wherein component (a) is present in an amount of from 0.025 wt% to 10 wt%.

30. (Previously presented) A composition according to claim 1, wherein component (b) is present in an amount of 0.025 wt% to 10 wt%.

31. (Previously presented) A composition according to claim 1, for use in the treatment of the human or animal body.

32. (Previously presented) The use of:

(a) an RSV fusion protein inhibitor as defined in claim 1; and

(b) a benzodiazepine derivative defined in claim 1, in the manufacture of a medicament for use in treating or preventing an RSV infection.

33. (Previously presented) The use according to claim 32, wherein component (a) is present in an amount of from 0.025 wt% to 10 wt% and component (b) is present in an amount of 0.025 wt% to 10 wt%.

34. (Previously presented) A product comprising:

(a) an RSV fusion protein inhibitor as defined in claim 1; and

(b) a benzodiazepine derivative as defined claim 1;

for separate, simultaneous or sequential use in the treatment of the human or animal body.

35. (Original) A product according to claim 34 for separate, simultaneous or sequential use in treating or preventing an RSV infection.

36. (Previously presented) A method of treating or preventing an RSV infection in a patient, which method comprises the administration to said patient of:

(a) an RSV fusion protein inhibitor as defined in claim 1; and

(b) a benzodiazepine derivative as defined in claim 1.

37. (Previously presented) The use of an RSV fusion protein inhibitor as defined in claim 1, in the manufacture of a medicament for use in treating or preventing an RSV infection, by co-administration with a benzodiazepine derivative as defined in claim 1.

38. (Previously presented) The use of a benzodiazepine derivative as defined in claim 1, in the manufacture of a medicament for use in treating or preventing an RSV infection, by co-administration with an RSV fusion protein inhibitor as defined in claim 1.

REMARKS

Claims 1-31 and 34-35 remain pending further examination while claims 32-33 and 36-38 are herein withdrawn. Claims 2, 19 and 23 are herein amended. Support for amended claim 2 can be found at least at page 9, lines 24-31. Support for amended claim 19 can be found at least at page 22, lines 14-31. Support for amended claim 23 can be found at least at page 4, lines 21-22. *No new matter is added.*

Based on the Office communication, the Examiner asserts that the instant application contains specie claims that lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Specifically, it is the Examiner's position that the species lack the same or corresponding special technical features because component (b) and general formula (V), has been disclosed by Bell *et al.*, J. Med. Chem., 11, pp 457-461. Particularly, the Examiner points to compound XLV at p.459, Table I of Bell *et al.* Moreover, the Examiner asserts that a species of component (a), of general formula (I), has also been disclosed by Yu *et al.*, in WO2002/26228 at p.29 (compound 10 therein).

The restriction requirement therefore requires Applicants to "define each of R^1-R^n, n, X and any other variables required for the elected species for component (b). The restriction requirement also requires Applicants to define each R^1-R^n, X, Y, n, Z, Q, A, B, L^1-L^n, and any additional variables as required for the elected species of component (a).

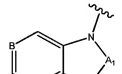
Applicants traverse the Restriction Requirement on the ground that the inventions of claims 1-38 possess a common special technical feature over Bell *et al.* and Yu *et al.* PCT Rule 13.2 states that claims shall fulfill the unity requirement "when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." Applicants respectfully bring the Examiner's attention to the fact that the claimed invention is directed to a novel composition, and methods of using the same, wherein said composition comprises a component (a) and a component (b). While components (a) and (b) are elements of the claimed inventions, they do not reflect the scope of the invention and are not themselves defined species. The common technical feature of claims 1-38 is the pharmaceutical

composition comprising both the inhibitor of the RSV fusion protein and the benzodiazepine derivative capable of inhibiting RSV replication. Each of the generic and species claims 1-38 are directed to this common technical feature. Neither Bell *et al.* nor Yu *et al.* anticipates, teaches, or suggests a composition comprising component (a) ***and*** (b) as defined in the instant application. Accordingly, all the generic and specie claims, 1-38, possess a common special technical feature over both Bell *et al.* and Yu *et al.*

Applicants further submit that the search and examination of all the claims will have substantial overlap, and no serious burden will result from searching and examining all claimed subject matter in the same application. In view of the identity of the claim elements, and the data bases and powerful computer search engines available to the Examiner, there would be no serious burden in examining all the claimed subject matter in a single application.

Accordingly, it is respectfully requested that the restriction requirement be withdrawn, and that all of the claimed subject matter presently pending in this application be examined.

Nevertheless, in compliance with the directives in the Office communication and in order to expedite prosecution of the instant application, Applicants elect composition claims 1-31 and 34-35 with traverse and make the following specie election.

For component (a), Applicants elect, ***with traverse***, 1-isopropenyl-3-(1-propyl-1H-benzoimidazol-2-ylmethyl)-1,3-dihydro-imidazo[4,5-c]pyridine-2-one wherein when component (a) is defined by generic compound (I), R^1, R^2, and R^3 are each hydrogen; -X is a direct link and -Y = H; Z = $-CR^6R'$ wherein R^6 = H and R' = propyl; Q = 

, wherein A_1 = -C(O), A_2 = -NR", R" = -isopropenyl, and B = N. This specie election is encompassed by claims 1-38.

For component (b), Applicants elect, ***with traverse***, (S)-1-(2-fluorophenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)urea wherein when component (b) is defined by generic compound (V) then R^1 = phenyl, R^2 = H, n = 0, R^4 = H, $R^5 = XR^6$ wherein X = -CO-, $R^6 = NR'R''$, wherein R' = H and R'' = phenyl substituted with fluorine. This specie election is encompassed by claims 1-38.

Applicants reserve the right to pursue the non-elected subject matter, in this or one or more subsequent patent applications.

As acknowledged by the Examiner, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. It is further Applicants' understanding that the election is for search purposes only and that the search will be extended to additional species upon a finding of allowable subject matter.

Applicants submit herewith the fee set forth in 37 C.F.R. 1.17(a). It is Applicants' understanding that this $2,350.00 fee is required for the petition for an extension of time for responding to the Restriction Requirement. However, should any additional fees be necessary, the Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-4876, under Order No. 117750-01801.

If a telephone conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned attorney at (617) 449-6500.

Dated: October 26, 2009

Respectfully submitted,

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